



Mitchell E. Daniels, Jr.  
Governor

Judith A. Monroe, M.D.  
State Health Commissioner

# Indiana State Department of Health

*An Equal Opportunity Employer*

## IN RE THE MATTER OF:

Rachelle Karpeles  
f'REAL! Foods  
37 Avenida de Orinda  
Orinda, CA 94563

**Re: Variance Request Dated June 12, 2008 and Section 296,  
Equipment food-contact surfaces and utensils; cleaning frequency requirements**

### Order to Deny a Variance

You are hereby notified that based on the recommendation of the Food Protection Program, Indiana State Department of Health (ISDH), and as authorized by Indiana Code (IC) 16-19-3-4.3 and IC 16-42-5-5.2, the State Health Commissioner hereby orders that a variance be denied to Rachelle Karpeles, f'REAL! Foods, 37 Avenida de Orinda, Orinda, CA 94563.

This variance denial is based on the variance application submitted on June 12, 2008 and supplemental information provided that ensued as a result of the review. As part of the review of variance application, ISDH representatives conducted on-site evaluations to determine how the procedures put into place were being administered and monitored.

### Order

This variance denial is based on the following criteria:

1. The laboratory studies detailing data collected on two different occasions did not meet the basic tenets of a properly conceived challenge study as per what is customary and usual in the field for these types of studies. Therefore, the data cannot be considered as acceptable in these instances.
2. Five facilities from the list of locations in the variance application were visited by staff members of the Food Protection Program to evaluate how these units were being operated in terms of actual use. One of the locations listed did not actually possess the unit, two of the locations were following the standard operating procedures (SOP) as provided by the company correctly and two locations **were not** following the procedures correctly. In the two that were not following the SOP's correctly, it was stated by store personnel that no one from f'REAL! Foods ever visited the store to provide training on how to use the product. This demonstrates a breakdown in continuity from the company to adequately provide and support the correct use of this unit.

3. Therefore, based on the fact that the challenge study data is flawed and that the SOPs are not being followed in all cases, it is necessary that your company comply with all provisions of Indiana State Department of Health Rule 410-IAC-7-24, including Section 296 on the timer intervals for cleaning frequency of food contact surfaces of equipment and utensils.

**If you wish to request an administrative review or stay of effectiveness of this decision pursuant to Ind. Code §4-21.5-3-7(a), you must petition for such review in writing. The petition must state facts demonstrating that:**

- a. you are a person to whom the decision is specifically directed;
- b. you are aggrieved or adversely affected by the decision; or,
- c. you are entitled to review under any law.

**Your request for review or stay of effectiveness must be filed in writing with the State Health Commissioner, 2 North Meridian Street, Indianapolis, Indiana 46204, on or before December 18, 2008. If no request for review or stay of effectiveness is filed by January 5, 2009, this decision shall become final.**

DATED AT INDIANAPOLIS, INDIANA, THIS 18th DAY OF DECEMBER 2008.

PURSUANT TO IC 16-19-3-4.3 AND IC 16-42-5-5.2, I HEREBY DENY A VARIANCE OF FOOD PROTECTION RULES AS STATED ABOVE.

JUDITH A. MONROE, M.D.  
STATE HEALTH COMMISSIONER

By: Terry A. Whitson  
Terry Whitson  
Assistant Commissioner  
Health Care Regulatory Services

By: Loren Robertson  
Loren Robertson  
Assistant Commissioner  
Public Health and Preparedness

cc: ISDH Food Protection Program Staff